

Notice of Allowability

Application No.

10/729,645

Examiner

Michael P. Barker

Applicant(s)

KUCERA ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/04/03.
2. ☒ The allowed claim(s) is/are 1-16.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 04/12/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 1
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EST

DETAILED ACTION

Claims 1-16 are currently pending in the instant application.

Priority

This application is a continuation-in-part of U.S. Application No. 10/166,979 which claims benefit of Provisional Application 60/297,460 and claims benefit of Provisional Application 60/297,729.

Information Disclosure Statement

Applicant's information disclosure statement (IDS), filed on April 12, 2004, has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Examiner's Amendment

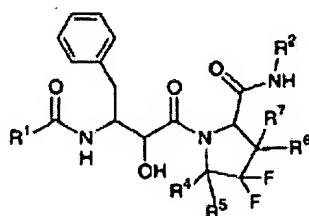
An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jeff H. Tidwell on September 16, 2005. The application has been amended as follows:

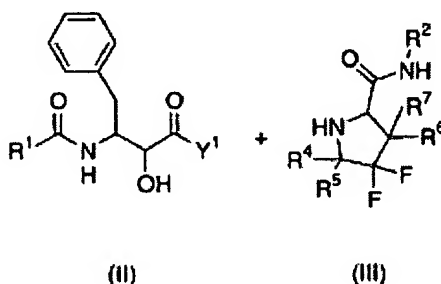
1. In **Claim 1**, page 1 (of the claims), lines 1 and 2, delete the words "pharmaceutically active metabolite".

Reasons for Allowance

The present invention is a process for preparing a compound of formula (I-H):

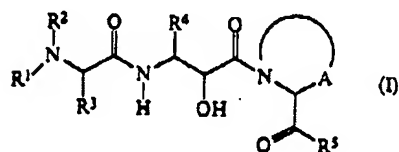


The claimed process comprises reacting a compound of formula (II), wherein Y¹ is a hydroxyl or a leaving group, with a compound of formula (III), or a salt or solvate thereof.



The novel and nonobvious aspect of this invention involves obtaining a compound of formula (I-H) by a DCC-mediated coupling of a compound of formula (II) with a compound of formula (III).

The closest prior art is Higashida et. al., European Patent No. 0587311 A1. Higashida discloses a process of synthesizing peptides that have the ability to inhibit the activity of HIV protease. Specifically, Higashida teaches a process for preparing a compound of formula (I),



which comprises reacting at least two peptides and/or amino acids

or reactive derivatives thereof and, if necessary, removing protecting groups, to form a

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compound of formula (I). Higashida's disclosed process results in a compound of formula (I), but, while similar to Applicant's claimed invention, does not teach or suggest Applicant's instantly claimed invention, nor does it provide motivation to one of ordinary skill in the art to synthesize a compound of formula (I-H) by combining a compound of formula (II) with a compound of formula (III).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality

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requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M-P. B. 09/16/2005

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KAMAL A. SAEED, PH.D.
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